REMARKS

Claims 2-3, 21, 22, 24 and 27 remain in this application. Applicants respectfully request reconsideration in view of the following remarks.

Applicants' Response to 35 U.S.C. §103 Rejection over Houser

Claims 3 and 21-22 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 6,361,559 to Houser et al. (hereinafter "Houser"). Applicants respectfully traverse the rejection on the grounds that the reference fails to teach or suggest Applicants' claims 3 and 21-22, and thus, fails to make out a *prima facie* case of obviousness.

The Examiner alleges that:

> Houser et al teach a vascular graft comprising an extruded composite of materials that are selected from a group including silicone and PTFE. It therefore would have been obvious for one of ordinary skill in the art to have provided for an extruded composite of silicone and PTFE, therefore an interpenetrating network of silicone and PTFE, as the group disclosed by Houser et al includes silicone and PTFE. Houser et al. therefore disclose an interpenetrating polymer network having discrete domains of silicone distributed throughout the PTFE that are extractable from the PTFE to create pores, as stated in paragraph 0035 of the specification, therefore permitting tissue ingrowth; Houser et al do not disclose a PTFE that is expanded or that has a node and fibril structure; a non-expanded PTFE having no node and fibril structure is therefore disclosed by Houser et al.
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> With regard to Claim 22, Houser et al fail to disclose a particle size of 5 to 100 microns. However, would therefore be obvious for one of ordinary skill to select particle size, through routine optimization, depending on the desired speed of mixing, as a composite is disclosed by Houser et al.
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> (Office Action, at page 3)

Claim 3 is directed to a vascular graft that includes the following:

> an implantable tubular extrudate, said tubular extrudate being extruded in the form of a tube, comprising an interpenetrating polymer network comprising a non-expanded PTFE matrix having no node and fibril structure, said matrix having distributed therein discrete domains of a solid extractable polymeric material, wherein upon exposure to sufficient dissolving medium or degradation temperature, said extractable polymeric material is extracted from said matrix to create pores in said tubular extrudate which upon implantation permit tissue ingrowth.

The Examiner has quoted the following passage of Houser to allege that claim 3 would be obvious to one of ordinary skill in the art:

> Synthetic bypass grafts may be manufactured by extruding, injection molding, weaving, braiding, or dipping polymers such as PTFE, expanded PTFE, urethane, polyamide, nylon, silicone, polyethylene, collagen, polyester or composites of these representative materials.
>
> (Houser, col 7, ll 3-7).

Houser is directed to a sutureless anastomosis system for securing a bypass graft to a host vessel or other tubular structure. The purpose of Houser is to provide a system to "position and secure bypass grafts at host vessel locations without stopping or rerouting blood flow". (Houser, col. 3, ll. 45-47). Nowhere in Houser is a vascular graft as described in the present invention disclosed or suggested.

Applicants' claim 3 specifically recites that the non-expanded PTFE has "no node and fibril structure." Rather than use the traditional process of expanding the PTFE to create pores by the formation of a node and fibril structure, the present invention creates pores in a non-expanded PTFE by first creating an IPN which contains a polymer that can be removed, and then removing the polymer to leave behind pores in the PTFE. This is distinctly different from Houser.

As previously argued by Applicants, an IPN is commonly understood in the art to mean a polymer containing two or more polymer networks, which are at least partially interlaced but not covalently bonded to each other. *See* IUPAC COMPENDIUM OF CHEMICAL TERMINOLOGY (2nd ed. 1997). More specifically, an IPN is a combination of two polymers in which at least one is synthesized and/or crosslinked in the immediate presence of the other to form an interlaced network. *See*, e.g.,U.S. Patent No. 4,764,560 to Mitchell; Col. 1, lines 63-66. Accordingly, a mixture of two or more separate and independently pre-formed polymer networks is not an IPN. *See* IUPAC COMPENDIUM OF CHEMICAL TERMINOLOGY.

Houser discloses synthetic bypass grafts that may include "extruding, injection molding, weaving, braiding, or dipping polymers". (Houser, col. 7, ll. 3-7). The possible polymers include ePTFE and silicone. Houser states that "these materials may be fabricated into a sheet or tubing using one or a combination of the stated manufacturing processes." (Houser, col. 7, ll. 7-9). However, nowhere in Houser is it disclosed, taught, or suggested that these two polymers are interlaced or interpenetrating in any manner. As commonly understood in the art, and defined above, Houser's potential combination of ePTFE and silicone cannot be considered an IPN.

Nowhere in either reference is it disclosed, taught or suggested to use an IPN of non-expanded PTFE having no node and fibril structure and another extractable polymer. Accordingly, Houser on its own lacks any teaching or suggestion of an IPN as recited in Claim 3 or the use of non-expanded PTFE in creating such an IPN. In fact, Houser suggests the opposite, i.e. no IPN and an ePTFE, which the ordinary person skilled in the art would understand to have a node and fibril structure because it is expanded. Thus, Houser fails to render claim 3, and any that depend therefrom, *prima facie* obvious.

Applicants' Response to 35 U.S.C. §103 Rejection over Houser in view of Chuter

Claim 2 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Houser in

view of U.S. Patent No. 6,293,969 to Chuter (hereinafter "Chuter"). Applicants respectfully traverse the rejection on the grounds that the combination of references fail to teach or suggest Applicants' claim 2, and thus, fails to make out a *prima facie* case of obviousness.

The Examiner acknowledges that Chuter fails to disclose a radially distensible stent positioned axially about the extrudage, however, the Examiner alleges that:

> Chuter teaches PTFE comprised in first and second stents with one stent positioned about the other stent for the purpose of obtaining a stent which is biologically inert. One of ordinary skill in the art would therefore have recognized the advantage of providing for the stent of Chuter in Houser et al., which comprises PTFE, depending on the desired inertness of the end product.
> It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a stent, therefore radially distensible, positioned axially about the tubular extrudate in Houser et al in order to obtain a stent which is biologically inert as taught by Chuter.
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> (Office Action, at page 4).

As stated in detail above, Houser does not disclose, teach or suggest an IPN with non-expanded PTFE matrix having no node and fibril and an extractable polymeric component that is to be implanted in the body and permits tissue ingrowth. Chuter was merely cited for its disclosure of a porous PTFE comprised in first and second stents. Nowhere in Chuter is an IPN that includes a non-expanded PTFE matrix having no node and fibril structure disclosed, taught or suggested. Therefore, Chuter fails to cure the deficiencies of Houser in this regard. Accordingly, the combination of Houser and Chuter fails to render claim 2 *prima facie* obvious.

Applicants respectfully submit that claim 2 is patentable over Houser and Chuter, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection based on this combination is respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Freiburger

Claims 24 and 27 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Statutory Invention Registration No. H1978 H to Freiburger et al. (hereinafter "Freiburger"). Applicants respectfully traverse the rejection on the grounds that the reference fails to teach or suggest Applicants' claims 24 and 27, and thus, fails to make out a *prima facie* case of obviousness.

In this rejection, the Examiner alleges that:

> Freiburger et al disclose an extrudate comprising an interpenetrating polymer network comprising PTFE and silicone; Freiburger et al do not disclose a PTFE that is expanded or that has a node and fibril structure; a non-expanded PTFE having no node and fibril structure is therefore disclosed by Freiburger et al; because Freiburger et al disclose an interpenetrating polymer network, Freiburger et al disclose discrete domains of the silicone distributed throughout the PTFE that are extractable to create pores, as stated in paragraph 0035 of the specification, therefore permit tissue ingrowth.
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> (Office Action of 12/27/2007, at page 3) (citations omitted).

The Examiner acknowledges that Freiburger fails to disclose silicone that is a solid particulate, but alleges that:

> Freiburger et al disclose a silicone, as discussed above. It would therefore be obvious for one of ordinary skill to select a solid particulate, a liquid silicone, as solid particulate and liquid are physical states of silicone.
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> (Office Action of 12/27/2007, at page 3).

The Examiner's assertions are respectfully traversed. Claim 24 relates to a PTFE extrudate that includes essentially "an interpenetrating polymer network comprising a non-

expanded PTFE matrix having no node and fibril structure" and "a solid particulate polymeric component which is incompatible with said non-expanded PTFE resin." The polymeric component includes discrete domains distributed throughout the non-expanded PTFE resin. The extraction of these domains creates pores in the PTFE resin. It is these pores that permit tissue ingrowth once the extrudate has been implanted in the body. Claim 27, which adds an additional limitation to claim 24, requires the solid extractable polymeric material to be silicone. As such, Applicants respectfully submit that the application of Freiburger towards claims 24 and 27 is improper and does not arrive at the presently claimed invention.

1. Freiburger is Nonanalogous Art

Freiburger is nonanalogous art. The presently claimed invention is directed to non-expanded porous PTFE products, in particular, grafts and stent-grafts. In contrast, Freiburger relates to monolithic films that have controlled breathability and include high water vapor transmission rate (hereinafter "WVTR") regions and low WVTR regions. In particular, the monolithic films of Freiburger are utilized to create absorbent undergarment or diaper training pants. Freiburger bears no relevance on the prosthesis field of art, nor the inventors' concerns in achieving a porous PTFE material to use in a variety of medical device products without requiring expansion to produce porosity. One of ordinary skill in the medical implantation art would not logically look to the field of absorbent undergarments for guidance with respect to non-expanded porous PTFE extrudates to be used as grafts and stent-products that are implanted in the body and permit tissue ingrowth.

Moreover by definition, if a reference is "nonanalogous art," it cannot be relied upon as a basis for rejecting an applicant's claims. As set forth in the case law, there are two criteria for determining whether or not a prior art reference is "analogous":

> (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the

inventor is involved.

In re Clay, 966 F.2d 656, 658-59, 23 U.S.P.Q.2d 1058, 1060-61 (Fed. Cir. 1992); *see also In re Oetiker*, 977 F.2d 1443, 1447, 24 U.S.P.Q.2d 1443, 1445 (Fed. Cir. 1992); *In re Deminski*, 796 F.2d 436, 442, 230 U.S.P.Q. 313, 315 (Fed. Cir. 1986).

A reference is only "reasonably pertinent" if it is one that "logically would have commended itself to an inventor's attention in considering his problem." *In re Clay*, 966 F.2d at 659.

As the court further explained in *In re Oetiker*:

> Patent examination is necessarily conducted by hindsight, with complete knowledge of the applicant's invention, and the courts have recognized the subjective aspects of determining whether an inventor would reasonably be motivated to go to the field in which the examiner found the reference, in order to solve the problem confronting the inventor. We have reminded ourselves and the PTO that it is necessary to consider 'the reality of the circumstances' - in other words, common sense - in deciding in which fields a person of ordinary skill would reasonable be expected to look for a solution to the problem facing the inventor.
>
> *In re Oetiker*, 977 F.2d at 1447 (citations omitted).

In accordance therewith, MPEP §2141.01(a) similarly expresses the standard that only references that relate to the field of an inventor's endeavor or that are reasonably pertinent to the particular problem to which an inventor is concerned with may be relied upon in formulating a rejection.

Freiburger's absorbable diaper is clearly outside the inventors' field of endeavor, i.e. fluid-tight implantable prostheses having sufficient porosity for tissue ingrowth. Freiburger is not at all concerned with the particular problems with which the inventors herein were

concerned. Freiburger seeks to solve the breathability problems associated with absorbent garments, which is an entirely different and unrelated problem than the problems addressed by the present invention, i.e. forming a porous PTFE graft without using the standard heat stretching, which creates a node and fibril structure.

a. **Applicants' problem was to obtain a porous PTFE material for use in a medical device without the cost and difficulty associated with conventional expanded PTFE whereas Freiburger's problem was to obtain a diaper with a breathable barrier**

As indicated in the specification of the present invention, the inventors were concerned with producing a porous PTFE material to be used in a medical device, without having to partake in the expensive costs and technical difficulties associated with the expanding techniques used for making the conventional ePTFE.

The problem of providing a porous PTFE that was not expanded involves a number of technical problems, none of which relate to absorbent diapers. In particular, the present invention requires that an extractable polymer is distributed throughout the IPN and PTFE matrix. This polymer is extracted when exposed to a sufficient degradation temperature or dissolving medium. A list of useful polymeric components and useful solvents were provided in Table I of the present application.

The overall purpose of the present invention is to create a porous medical device that can be implanted in the body and permit tissue ingrowth. The tissue ingrowth process is partially dependent on the ability of blood cells to pass through the porous device. Blood cells are typically approximately 6-8 microns in diameter, and the pores created by the present invention permit cell penetration, while maintaining a fluid-tight graft.

b. Freiburger's problem was to obtain a diaper with a breathable barrier

In contrast, Freiburger is directed to a monolithic film, which is defined as "non-porous". (Freiburger, col. 3, ll. 10-11). The film has "passages with cross-sectional sizes on a molecular scale formed by a polymerization process." (Freiburger, col. 3, ll. 13-14). The purpose of these passages is so water or liquids can diffuse through the monolithic film "as a result of a concentration gradient" and are re-evaporated into the air. (Freiburger, col. 6, ll. 60-col. 7, ll. 7). However, as stated in the detailed description, "monolithic film provides an absolute barrier to liquids, bacteria, and viruses as no pores are present in the film...no liquid flow is possible unless the film ruptures." (Freiburger, col. 7, ll. 17-30.) Freiburger even specifically states that "holes are never intentionally introduced into the film." (col. 7, l. 52).

As stated above, blood cells are typically approximately 6-8 microns in diameter. Typically bacterial molecules are in the size range of 0.5-5 microns and typical viruses are in the size range of 10-30 nm. Both of the ranges are below the size that would permit red blood cell penetration, a necessary precondition to tissue ingrowth. Thus, Freiburger actually teaches away from the pore size that would encourage tissue ingrowth. Therefore one of ordinary skill in the art would not look to Freiburger's non-porous monolithic film, which is a complete barrier to bacteria and virus particles, to create a PTFE extrudate as described above for implantation in the body with any expectation of success.

Furthermore, the Examiner has misapplied the reference. The Examiner claims that Freiburger discloses an IPN with discrete extractable domains that are extractable. However, nowhere in Freiburger is such a phenomena described. Freiburger describes "a polymer/polymer composite combining polydimethyl siloxane and polytetrafluoroethylene in an interpenetrating polymer network." This combination is the final product of Freiburger. This is in contrast to the present invention, where a polymer is extracted to create a porous PTFE structure that permits tissue ingrowth. The focus of the present invention is to distribute

pores or voids throughout the PTFE matrix by using an extractable polymeric component. Without the extractable polymeric component, the IPN would not be porous and would not permit tissue ingrowth. In stark contrast, Freiburger explicitly states that holes are undesirable and "never intentionally introduced into the film." (Freiburger, col. 7, l. 52). Freiburger does not remove the siloxane from her matrix because that would be contrary to the intent of her invention.

The Examiner alleges that one of ordinary skill in the art would have utilized the teachings of Freiburger to modify the pore size in order to have pores that permit tissue ingrowth. Applicants respectfully submit that such an assertion is incorrect. Not only does Freiburger disclose a wholly different material than that of the present invention, the monolithic film discussed in Freiburger acts as a complete barrier to bacteria and viruses. One of ordinary skill in the art would not look to Freiburger's non-porous monolithic film, which is a complete barrier to bacteria and virus particles, to create a PTFE extrudate as described above for implantation in the body with any expectation of success.

In closing, the following table illustrates a number of contradictory features between Freiburger and the present invention:

Inventive Composition Characteristics	**Freiburger Composition Characteristics**
Class 623: Prosthesis, parts thereof, or aid, and accessories thereof	Class: 156: Adhesive bonding and miscellaneous chemical manufacture
Prosthesis implantable in the body	Absorbent garment to be worn outside the body
Pore size of between 5 and 100 microns	Does not have pores
Pore size permits tissue ingrowth in the prosthesis	Passages with cross-sectional sizes on a molecular scale only permit liquid vapors to diffuse through the film
Pores are large enough to allow blood cells to pass through	Passages are a complete barrier to liquids, bacteria and viruses
Includes a solid particulate that is incompatible with the non-expanded PTFE and can be extracted	Holes are never intentionally introduced into the film

Applicants respectfully submit that claims 24-27, and any claims with depend therefrom, are patentable over Freiburger. Reconsideration and withdrawal of the Section 103 rejection based on this combination is respectfully requested.

Having responded in full to the present Office Action, it is respectfully submitted that the application is in condition for allowance. Favorable action thereon is respectfully solicited.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,

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